October 10, 2019

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Verma,

We, the undersigned, ask for your attention as the U.S. is facing an unprecedented epidemic of hepatitis C infections to which state Medicaid programs are failing to adequately respond.

Since the advent of highly effective curative hepatitis C (HCV) treatments, we have been able to avert thousands of premature deaths and improve the quality of life for Americans cured of the viral infection; however, there is much more work to be done. There are at least 2.4 million Americans[1] currently infected with HCV, and HCV infection kills about 20,000 Americans per year – more people than all 60 nationally notifiable infectious diseases combined[2]. Untreated HCV is contributing to increases in liver cancer, which has become the fastest-growing cause of cancer mortality in the U.S[3]. Unfortunately, the nation has also been unsuccessful in preventing new HCV infections. Recent data from the Centers for Disease Control and Prevention (CDC) has demonstrated that acute cases of hepatitis C infection have more than tripled since 2010 driven by an increase in unsafe injection drug use[4]. Moreover, a failure to respond to the epidemic in adults of child-bearing age has resulted in increases in vertical transmission; in 2017 alone, there were at least 18,927 newborns born exposed to hepatitis C[5]. Persons representing certain racial and ethnic minorities are dying at disproportionate and increasing rates from hepatitis C infection[4].

As you are aware, the Centers for Medicare and Medicaid Services (CMS) oversees the care of many persons living with hepatitis C. Persons insured under Medicaid have an 3-fold higher prevalence of hepatitis C compared to their privately insured counterparts[6]. As of 2017, one-third of those chronically-infected with hepatitis C had already reached Medicare eligible age, with an additional one-half becoming eligible within the next decade[4]. As such, leadership from CMS is central in comprehensively addressing the nation's response to this public health crisis. Medical and public health leaders have called for all persons infected with hepatitis C to be offered curative therapy with hepatitis C direct-acting antivirals (DAA). The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) HCV treatment panel, "*recommend treatment for all patients with chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy."*[7]

Since the release of *Hepatitis C: State of Medicaid Access*[8] and the increased transparency to egregious HCV treatment restrictions in states' Medicaid programs, many states have loosened or removed restrictions to these life-saving curative treatments. Unfortunately, several state Medicaid programs are still standing in the way of the medical standard of care by imposing discriminatory prior authorization criteria to restrict access based on liver disease severity, provider specialty, and substance use. CMS made clear to state Medicaid programs in a letter dated November 5, 2015 that prior authorization criteria '*should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infection.*[9]' Despite this clear guidance, further outlined by

section 1927(b) of the Social Security Act, more than half of all state Medicaid program still deny medically necessary coverage to Medicaid enrollees with hepatitis C infection. Even in states that have removed restrictions, we are still seeing some managed care organization imposing treatment restrictions, in violation of CMS guidance. Since the guidance, numerous courts have agreed that restricting access to medically necessary coverage violates federal Medicaid law[10]. For a complete overview of state practices developed by the National Viral Hepatitis Roundtable and the Harvard Center for Health Law and Policy Innovation we encourage you to visit www.StateofHepC.org.

We would like to bring to your attention several important medical and public health implications of hepatitis C treatment restrictions;

1.) *Liver disease severity*: Waiting for liver disease to progress before approving hepatitis C curative therapy reduces the efficacy of direct-acting antivirals[11] and puts persons at increased risk of developing many of the sequalae of HCV infection, including hepatocellular carcinoma[12]. Also, given the contribution of older age to liver disease severity, younger adults of child-bearing age may be less likely to demonstrate advanced liver disease. Thus, waiting for liver disease to progress may be contributing to increases in hepatitis C vertical transmission.

2.) *Specialist requirement*: Requiring an infectious disease or gastroenterology specialist to prescribe HCV therapy is not warranted given the ease and simplicity of treating most patients. According to IDSA/AASLD guidance, *"the short duration of treatment and few serious adverse events associated with (HCV) DAA therapy present an opportunity to expand the number of midlevel practitioners and primary care physicians engaged in the management and treatment of HCV infection."* Requiring treatment by or in consultation with a specialist provider is placing undue burden on persons with hepatitis C living in underserved areas, particularly those in rural areas where patients may have to travel hundreds of miles to reach a specialist.

3.) *Substance use:* Requiring screening for substance or alcohol use is not based on clinical evidence. According to IDSA/AASLD guidance, "*There are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy."* Any concerns that persons who inject drugs may be nonadherent have been countered by several studies which have demonstrated high adherence and low rates of reinfection[13-16]. Given that unsafe injection drug use drives most new HCV infections, scaling up HCV treatment among persons who use drugs represents an opportunity to positively impact HCV incidence; a benefit clearly outlined in a report on viral hepatitis elimination by the National Academies of Sciences[17].

Moreover, requiring that patients demonstrate sobriety unfairly places additional burden on, and limits access to treatment for, persons with a comorbid medical condition. We believe that denying life-saving HCV treatment to persons with substance use disorder may constitute a violation of Americans with Disabilities Act. Specifically, Section 504 of the 1973 Rehabilitation Act prohibits discrimination against people with disabilities in programs that receive federal financial assistance.

We call upon CMS to take seriously this continued state-sanctioned discrimination impacting persons living with hepatitis C throughout the United States. Please do your part to prioritize this issue and to call upon state Medicaid programs to comply with federal law and open access to curative hepatitis C therapy. We look forward to setting our nation on the path towards viral hepatitis elimination, but we cannot do so without your leadership.

Sincerely,

National Viral Hepatitis Roundtable

Center for Health Law & Policy and Innovation at Harvard Law School

Hepatitis Education Project

World Hepatitis Alliance

Sources

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